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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,888

03/23/2007

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4033. 3004 US

8755

38473 7590 04/24/2009
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EXAMINER

HEINCER, LIAM J

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

04/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,888	Applicant(s) WHITE ET AL.	
	Examiner Liam J. Heincer	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,9 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,9 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/12/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 9, 15, 16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al. (US Pat. 6,224,893).

Considering Claims 7, 9, and 18: Langer et al. teaches a method of making a semi-interpenetrating network (3:5-21) comprising a blend of ionically and covalently crosslinkable polymers where the covalently crosslinkable polymer is crosslinked (10:8-20). Langer et al. teaches the ionically crosslinkable polymer as optionally being hyaluronic acid (4:50-5:2) and the covalently crosslinkable as optionally being a water soluble chitosan (6:46-50). Since Langer et al. teaches the ionic compound as not being crosslinked, the reaction conditions would inherently be such that the amine groups would not be protonated, and the hydroxyl groups are not reacted, as these would result in the crosslinking of the hyaluronic acid.

Langer et al. does not teach the combination of chitosan and an anionic polysaccharide with sufficient specificity. However, Langer et al. does teach each of the components as being one of a finite number of possible alternatives. It would have been obvious to a person having ordinary skill in the art at the time of invention to have used the combination of chitosan and an anionic polysaccharide, and the motivation to do so would have been that it is obvious to choose from a finite list of predictable, known options with a reasonable expectation of success. See MPEP § 2143.

Langer et al. does not teach the claimed pH. However, Langer et al. does teach that the pH affects the degree of crosslinking of ionically crosslinkable polymers (1:27-29). Generally, differences in reaction conditions are not sufficient to support patentability. See MPEP § 2144.05. It would have been obvious to a person having ordinary skill in the art at the time of invention to have optimized the pH through routine optimization, and the motivation to do so would have been, as Langer et al. suggests, to reduce the crosslinking of the ionic component (1:27-29), thus providing a semi-interpenetrating network which has advantageous degradation properties and enhance mechanical properties (10:8-20).

Considering claims 15 and 16: Langer et al. teaches using chitosan (6:46-50). Chitosan is by definition deacetylated chitin. As deacetylated chitin is listed as a derivative of chitosan in claim 16, chitosan would then fall under the scope of derivative of chitosan as presented in the claims.

Considering Claim 19: Langer et al. teaches the network as additionally comprising other components of the extra cellular matrix in a blend with hyaluronic acid (4:1-8).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al. (US Pat. 6,224,893) as applied to claim 7 above, and further in view of the evidence of Hudson et al. (Chitin and Chitosan).

Considering Claim 17: Langer et al. teaches the method of claim 7 as shown above. Langer et al. also teaches the chitosan as being soluble in water (6:46-50).

Langer et al. is silent towards the acetylation content of the chitosan. However, “[W]here the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2144.05. As Hudson et al. shows that the acetylation degree of the chitosan is directly related to the solubility of the chitosan in water (Section 4.1), a person having ordinary skill in the art at the time of invention would consider the acetylation degree to be a result effective variable. As such, it would have been obvious to a person having ordinary skill in the art at the time of invention to have optimized the acetylation content of the chitosan of Langer et al. through routine optimization, and the motivation to do so would have been to obtain a water soluble chitosan for the crosslinking reaction.

Response to Arguments

Applicant's arguments with respect to claims 7, 15, 18, and 19 with regard to the rejection under 35 U.S.C. § 102(b) and 15 and 16 with regard to the rejection under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed January 12, 2009 with respect to the rejection of claims 8 and 9 under 35 U.S.C. 103(a) have been fully considered but they are not persuasive, because:

A) Applicants argument that chitosan is not a water soluble derivative of a basic polysaccharide is not persuasive. Langer et al. specifically refers to the chitosan used in the invention as being water soluble (6:46-50). As Hudson et al. shows that derivatives of chitosan are water soluble (Section 4.1), a person having ordinary skill in the art at the time of invention would have known to choose a water soluble derivative for the semi interpenetrating network.

Additionally, the original claims list chitosan as a water soluble polysaccharide (See original claim 2). Therefore, it is clear that chitosan falls under the definition of water soluble polysaccharides as presented by the applicant in the original specification and claims. Finally, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which

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applicant relies (i.e., the chitosan being soluble at neutral or basic pH) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

B) Applicants argument that chitosan is a non preferred embodiment is not persuasive. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). See MPEP § 2123. While the examples of Langer et al. clearly prefer free radical crosslinkable covalently crosslinked species, the reference discloses an embodiment where chitosan is crosslinked by isocyanates or aldehyde crosslinkers in solution.

C) Applicant's argument that Langer et al. is only concerned with crosslinking the hyaluronic acid is not persuasive. Although Langer et al. does refer to gelling/crosslinking the hyaluronic acid (4:50-5:2), this is one of several embodiments presented in the reference. Langer et al. is also concerned with semi interpenetrating networks comprising a blend of ionically and covalently crosslinkable polymers where the covalently crosslinkable polymer is crosslinked (10:8-20). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). See MPEP § 2123.

D) Applicant's argument that pH is not a result effective variable is not persuasive. Langer et al. states that the pH controls the crosslinking along with ionic strength and temperature of ionically crosslinked polysaccharides (1:27-29). Therefore, the reference also implicitly teaches that the pH controls whether the ionic polysaccharide does not crosslink. Further, the sections of WO 94/25080 cited by the applicant (see page 8 of applicants arguments) to show that hyaluronic acid crosslinks at physiological pH are both directed towards alginate, not hyaluronic acid. As such, the

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reference does not teach away from the claimed invention where hyaluronic acid does not crosslink at the claimed pH.

E) Applicants argument that Hudson et al. deals with deacetylated chitin rather than acetylated chitosan is not persuasive. As shown by Hudson et al., chitin and chitosan differ only by a degree of acetylation (Section 1). As such, deacetylated chitin and acetylated chitosan would be the same compound, not independent species.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liam J. Heincer whose telephone number is 571-270-3297. The examiner can normally be reached on Monday thru Friday 7:30 to 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/

Supervisory Patent Examiner, Art Unit 1796

LJH

April 21, 2009